Revumenib Data Update Call with Dr. Ghayas Issa and Dr. Eytan Stein

Syndax

DECEMBER 11TH, 2022 – ASH ANNUAL MEETING

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Revumenib as a first- and best-in-class treatment

Syndax goals at the American Society of Hematology Annual Meeting

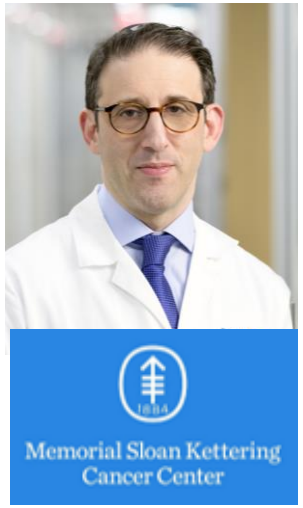
- Physician engagement
- Disease awareness and education
- To present data that supports revumenib's potential to change the treatment paradigm in acute leukemia

Today's guest speakers: AUGMENT-101 Principal Investigators

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Ghayas Issa, MD

- Hematology & Oncology, Departments of Leukemia and Genomic Medicine, MD Anderson Cancer Center
- Assistant Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center
- Translational research on leukemia genetics
- Principal investigator, MDACC Moon Shot Program on AML MRD



Eytan Stein, MD

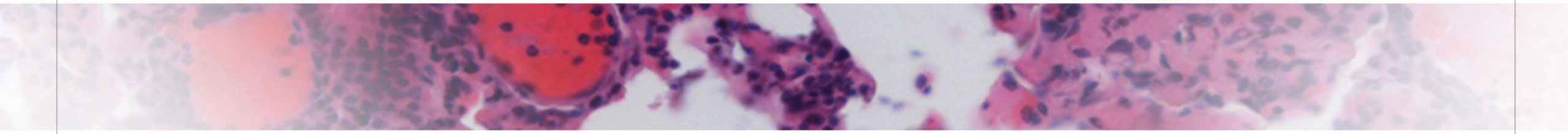
- Chief, Leukemia Service, Director, Program for Drug Development in Leukemia, Associate Attending Physician Memorial Sloan Kettering Cancer Center
- Led clinical studies of enasidenib, ivosidenib and pinometostat
- Extensive Phase 1 experience with novel compounds targeting IDH, PRMT5, DHODH, and Menin-MLL interaction
- Lead investigator at MSKCC for BEAT AML

Dr. Ghayas Issa

Assistant Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center

A Focus on the Phase 1 Data from Augment 101

American Society of Hematology
Helping hematologists conquer blood diseases worldwide



The Menin Inhibitor Revumenib (SNDX-5613) Leads to Durable Responses in Patients with *KMT2A*-Rearranged or *NPM1* Mutant AML: Updated Results of a Phase 1 Study

Ghayas C. Issa, MD,[1] Ibrahim Aldoss, MD,[2] John F. DiPersio, MD, PhD,[3] Branko Cuglievan, MD,[1] Richard M. Stone, MD,[4] Martha L. Arellano, MD,[5] Michael Thirman, MD,[6] Manish R. Patel, MD,[7] David Dickens, MD,[8] Shalini Shenoy, MD,[3] Neerav Shukla, MD,[9] Galit Rosen, MD,[10] Rebecca G. Bagley, MA,[10] Michael L. Meyers, MD, PhD,[10] Kate Madigan, MD,[10] Peter Ordentlich, PhD,[10] Yu Gu, PhD,[10] Steven Smith, BS,[10] Gerard M. McGeehan, PhD,[10] and Eytan M. Stein, MD[9]

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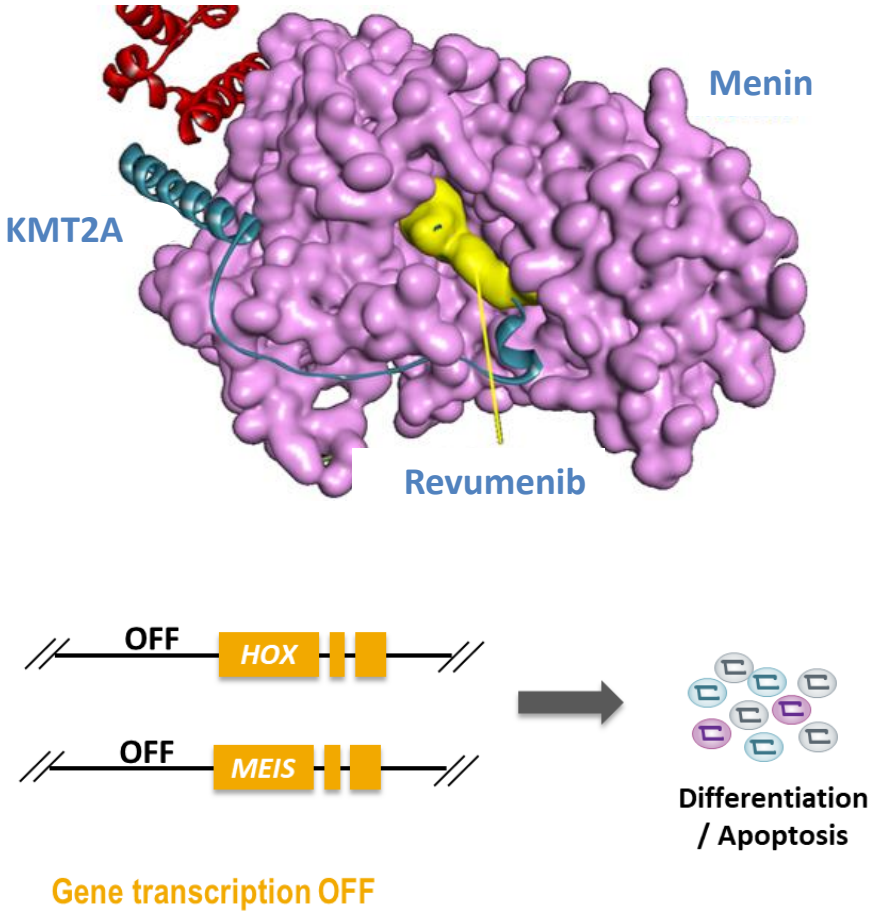
Revumenib (SNDX-5613) is a potent, selective menin-KMT2A interaction inhibitor

- The menin-KMT2A interaction is a critical dependency in *KMT2Ar* (*MLL1r*) and *mNPM1* leukemias responsible for the leukemogenic gene expression
  - *KMT2Ar*: ~ 10% AML or ALL (~ 80% infant ALL)[1]
  - *mNPM1*: ~ 30% AML[2]
- Revumenib competitively binds a discrete, well-defined pocket within menin, where both wild-type KMT2A (MLL1) and KMT2A fusion proteins bind

  → disassembling abnormal transcription complexes in *KMT2Ar*, *mNPM1*, and other leukemia subtypes[3]

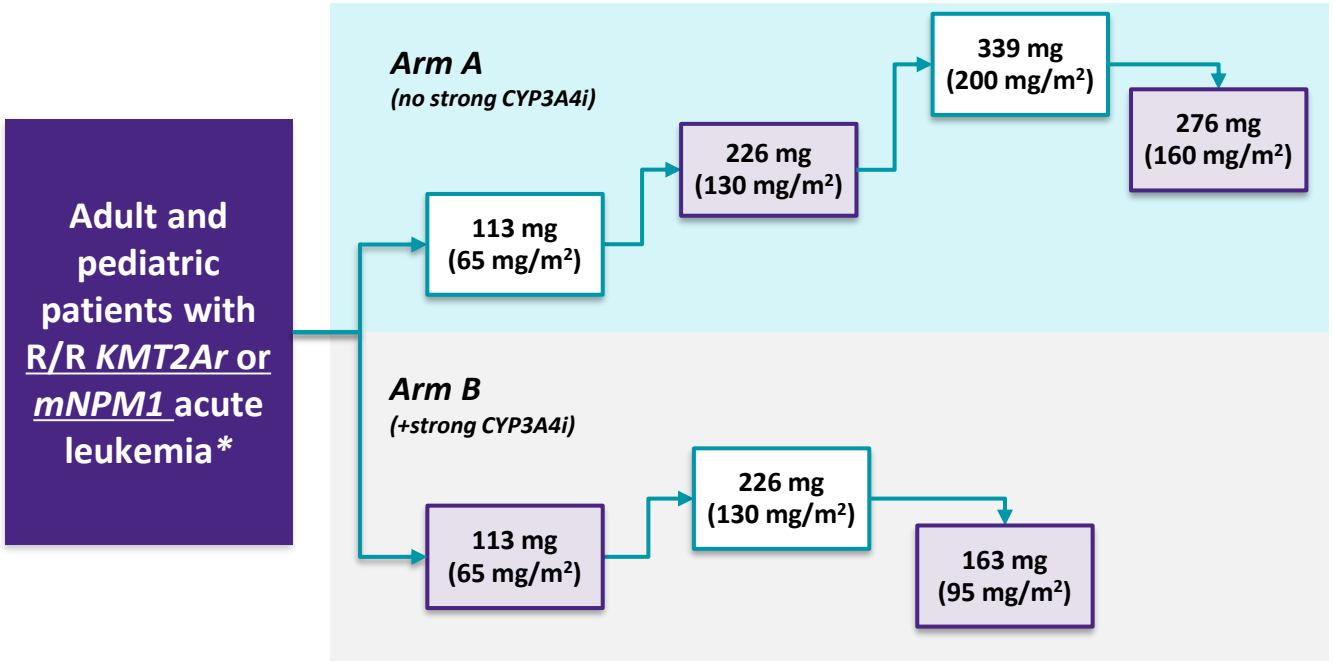


1. Issa GC, et al. *Leukemia.* 2021;35:2482–2495; 2. Papaemmanuil, E. *et al. N Engl J Med.* 2016;374: 2209-2221; 3. Krivtsov A, et al. Cancer Cell. 2019;36(6):660-673.
ALL, acute lymphoblastic leukemia; AML, acute myeloid leukemia; *KMT2Ar*, lysine methyltransferase 2A rearrangements; *MLLr*, mixed lineage leukemia rearranged; *mNPM1*, mutated nucleophosmin 1.

AUGMENT-101 Phase 1 study design and objectives

Treatment

- Revumenib oral, q12h continuous dosing, 28-day cycle
- Accelerated titration into a rolling 6 design



Primary objectives

- Characterize safety, tolerability, PK, and RP2D

Prespecified RP2D selection criteria

- No more than 1 of 6 of evaluable patients experience a DLT
- At least 2/3 of patients receive ≥ 80% of their dose in the first two cycles
- 24-hour AUC (AUC0-24) exceeds 15,000 ng×hr/mL in at least 2/3 of patients

Exploratory objectives

- Anti-leukemic activity within *KMT2Ar* or *mNPM1* population

Populations

- Safety (pts ≥ 1 dose revumenib): N=68
- Efficacy (*KMT2Ar* or *mNPM1)*: N=60

*Protocol originally allowed any R/R leukemia regardless of genotype but was amended to *KMT2Ar* or *mNPM1* patients only. A majority of patients (n=60; 88%) were *KMT2Ar* or *mNPM1* and evaluable as the efficacy population.
AUC, area under the curve; DLT, dose-limiting toxicity; PK, pharmacokinetics; q12h, every 12 hours; RP2D, recommended Phase 2 dose; R/R, relapsed or refractory.

AUGMENT-101 patients are heavily pretreated with a poor prognosis

Baseline Characteristics	Safety Population N=68
Median age, years (range)	42.5 (0.8, 79)
Adult (n=60)	50.5
Pediatric (n=8)	2.5
Female, n (%)	42 (62)
Leukemia type, n (%)	
AML	56 (82)
ALL	11 (16)
MPAL	1 (2)
Median prior therapies (range)	4 (1,12)
Stem cell transplant, n (%)	31 (46)
Venetoclax, n (%)	41 (60)

Baseline Characteristics	Safety Population N=68
***KMT2Ar*, n (%)**	46 (68)
t(9;11)	10 (15)
t(11;19)	9 (13)
t(4;11)	6 (9)
t(6;11)	3 (4)
t(11;17)	2 (3)
Other	16 (24)
***mNPM1*, n (%)**	14 (21)
***KMT2A* and *NPM1* wild type, n (%)**	8 (12)
Co-occurring mutations*, n (%)	
FLT3	14 (25)
RAS	12 (29)
TP53	4 (10)

*In patients for whom co-occurring mutation data were available.
MPAL, mixed-phenotype acute leukemia

Data cutoff: 31 March 2022

2 patients with treatment ongoing and 12 patients proceeded to HSCT while in remission

Patient Disposition	Safety Population N=68
Treatment Ongoing, n (%)	**2 (3)**
Discontinued Treatment, n (%)	**66 (97)**
Progressive disease/No response	39 (57)
Transplant	12 (18)
Adverse event (all unrelated)	7 (10)
Withdrew consent	3 (4)
Other*	3 (4)
Physician decision	2 (3)

*Other: death (not related to treatment), n=2; donor lymphocyte infusion, n=1
HSCT, hematopoietic stem cell transplant.

Data cutoff: 31 March 2022

Adverse Events across all doses of revumenib

Any-grade treatment-related AE (≥5%)	Safety Population N=68
Patients with ≥1 treatment-related AE, n (%)	53 (78)
ECG QTc prolonged	36 (53)
Nausea	18 (27)
Vomiting	11 (16)
Differentiation syndrome	11 (16)
Diarrhea	7 (10)
Dysgeusia	5 (7)
Decreased appetite	5 (7)

No treatment discontinuations for QTc prolongations, or associated arrhythmias

≥Grade 3 treatment-related AE	Safety Population N=68
Patients with ≥Gr 3 treatment-related AE, n (%)	11 (16)
ECG QTc prolonged	9 (13)
Diarrhea	2 (3)
Anemia	2 (3)
Asthenia	1 (2)
Fatigue	1 (2)
Hypercalcemia	1 (2)
Hypokalemia	1 (2)
Neutropenia	1 (2)
Thrombocytopenia	1 (2)
Tumor lysis syndrome	1 (2)

10% of patients (5/52) had Gr 3 QTc prolongation at doses meeting criteria for RP2D

ECG, electrocardiogram; QTc, corrected QT interval.

Data cutoff: 31 March 2022

Revumenib demonstrates promising antileukemic activity in relapsed/refractory *KMT2Ar* and *mNPM1* leukemias

Best Response, n (%)	Efficacy Population n=60	
ORR*	**32/60 (53%)**	
Best Response		
CR	12 (20%)	
CRh	6 (10%)	
CRp	5 (8%)	
MLFS	9 (15%)	
MRD^{neg} rate†	**18/32 (56%)**	
CR/CRh MRD^{neg}	14/18 (78%)	
CR/CRh/CRp MRD^{neg}	18/23 (78%)	
Genetic alteration	***KMT2Ar* n=46**	***mNPM1* n=14**
ORR	**27/46 (59%)**	**5/14 (36%)**
CR/CRh	15 (33%)	3 (21%)
CR/CRh MRD^{neg} rate	11/15 (73%)	3/3 (100%)

CR/CRh
18 (30%)

Data cutoff: 31 March 2022

*Overall Response Rate = CR + CRh + CRp + MLFS; †MRD status assessed locally by PCR or MCF

CR, complete remission; CRh, complete remission with partial hematologic recovery; CRp, complete remission with incomplete platelet recovery; MLFS, morphologic leukemia free state; MRD, measurable residual disease.

Revumenib demonstrates promising antileukemic activity in relapsed/refractory *KMT2Ar* and *mNPM1* leukemias

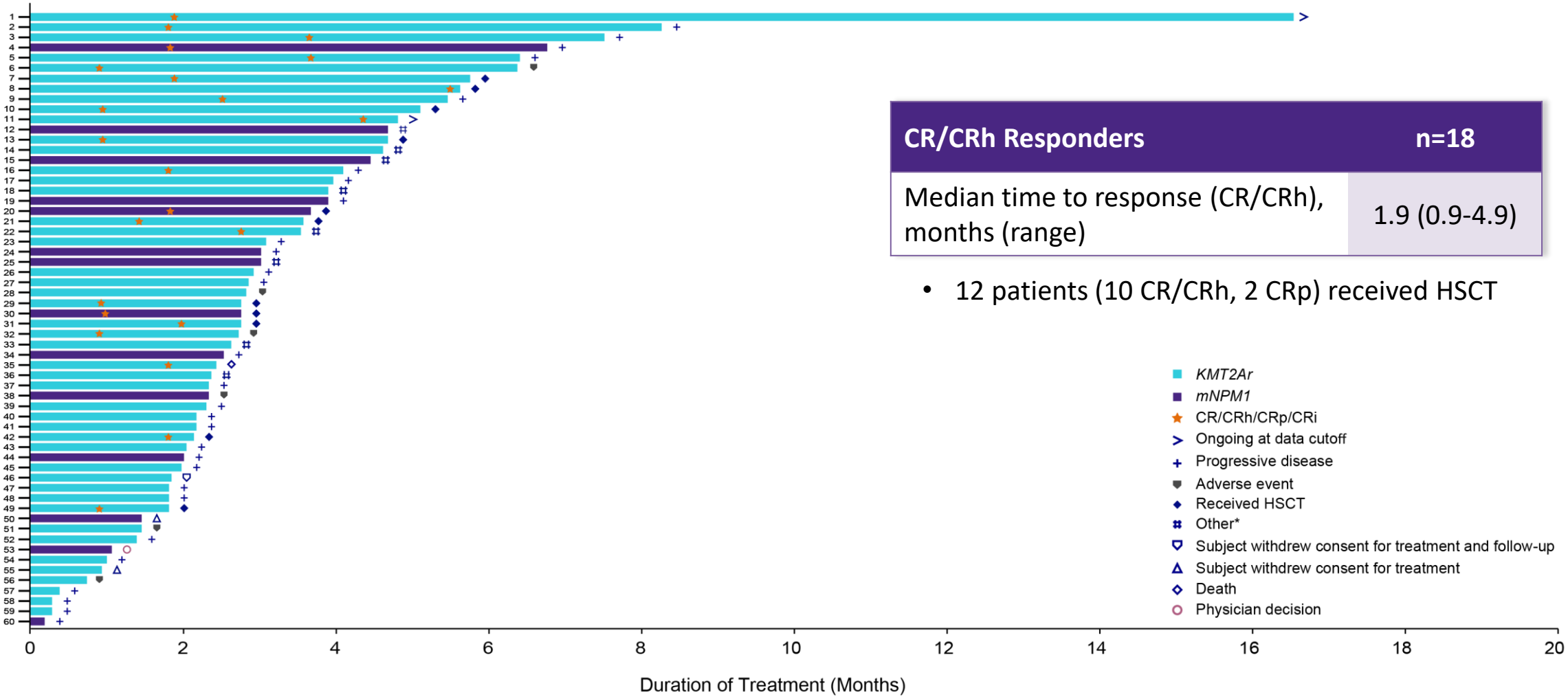
Best Response, n (%)	Efficacy Population n=60		Efficacy Population Doses Meeting Criteria for RP2D n=48	
ORR*	**32/60 (53%)**		**25/48 (52%)**	
Best Response				
CR	12 (20%)		8 (17%)	
CRh	6 (10%)		5 (10%)	
CRp	5 (8%)		5 (10%)	
MLFS	9 (15%)		7 (15%)	
MRD^{neg} rate†	**18/32 (56%)**		**14/25 (56%)**	
CR/CRh MRD^{neg}	14/18 (78%)		10/13 (77%)	
CR/CRh/CRp MRD^{neg}	18/23 (78%)		14/18 (78%)	
Genetic alteration	***KMT2Ar* n=46**	***mNPM1* n=14**	***KMT2Ar* n=37**	***mNPM1* n=11**
ORR	**27/46 (59%)**	**5/14 (36%)**	**20/37 (54%)**	**5/11 (46%)**
CR/CRh	15 (33%)	3 (21%)	10 (27%)	3 (27%)
CR/CRh MRD^{neg} rate	11/15 (73%)	3/3 (100%)	7/10 (70%)	3/3 (100%)

Data cutoff: 31 March 2022

*Overall Response Rate = CR + CRh + CRp + MLFS; †MRD status assessed locally by PCR or MCF

CR, complete remission; CRh, complete remission with partial hematologic recovery; CRp, complete remission with incomplete platelet recovery; MLFS, morphologic leukemia free state; MRD, measurable residual disease.

Duration of revumenib therapy in patients with *KMT2Ar* or *mNPM1*



CR/CRh Responders	n=18
Median time to response (CR/CRh), months (range)	1.9 (0.9-4.9)

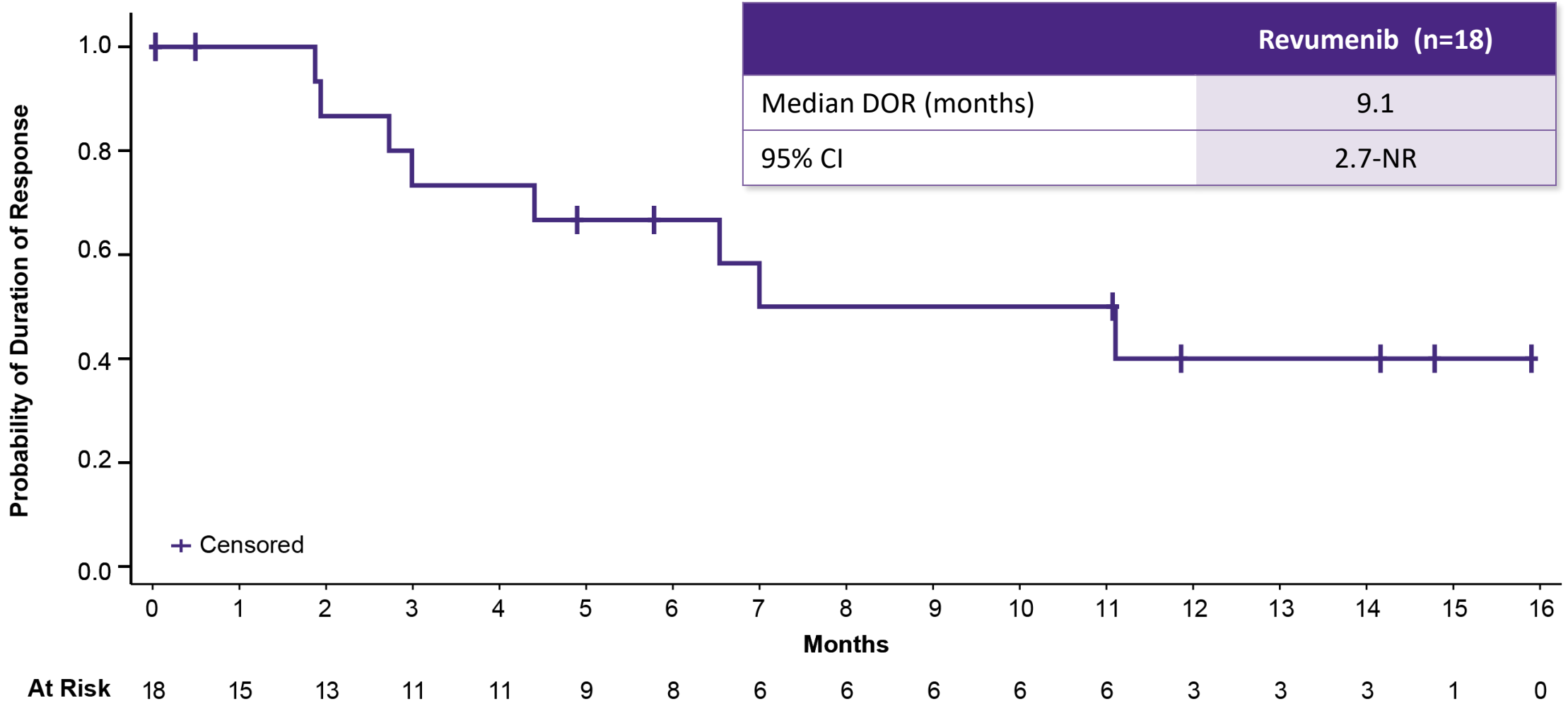
- 12 patients (10 CR/CRh, 2 CRp) received HSCT

*Other reasons for treatment discontinuation included no response, relapse, death, and donor lymphocyte infusion.

Data cutoff: 31 March 2022

Duration of CR/CRh response with revumenib treatment

	Revumenib (n=18)
Median DOR (months)	9.1
95% CI	2.7-NR

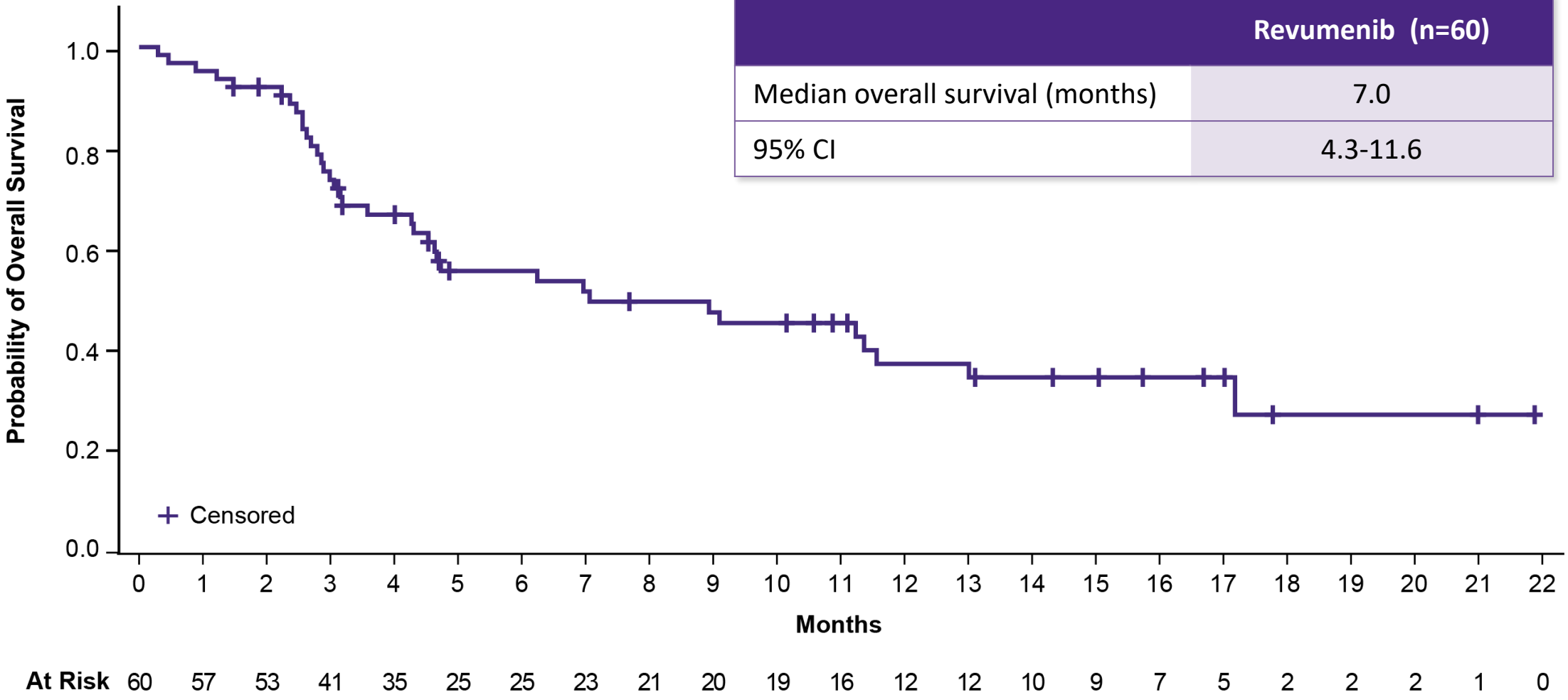


DOR, duration of response; NR, not reached.

Data cutoff: 31 March 2022

Overall survival in revumenib treated patients with *KMT2Ar* or *mNPM1*

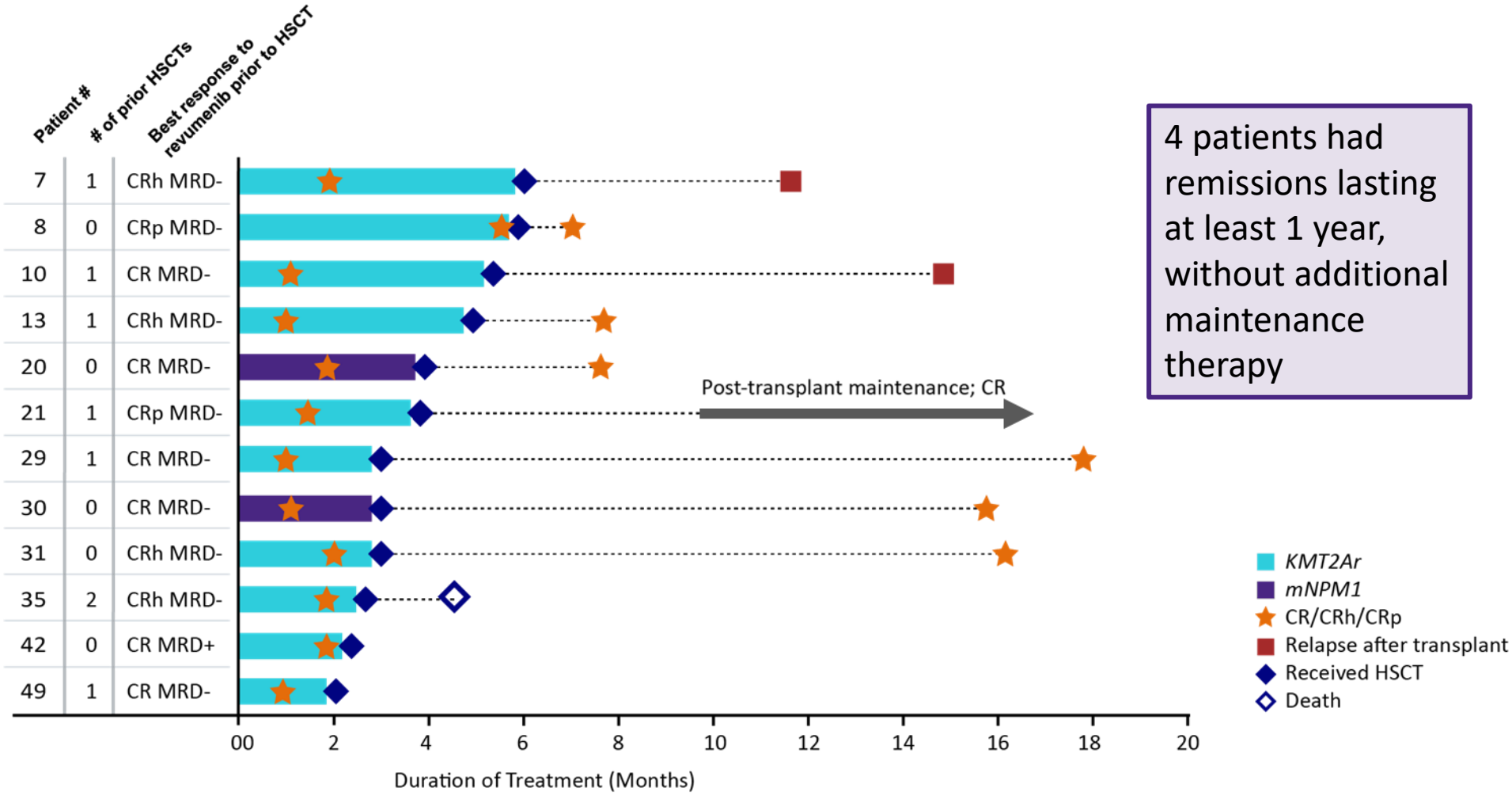
	Revumenib (n=60)
Median overall survival (months)	7.0
95% CI	4.3-11.6



Data cutoff: 31 March 2022

Duration of revumenib treatment and response status

- 38% of responders in AUGMENT-101 proceeded to transplant
- Patients with CR, CRh, and CRp after revumenib monotherapy went on to receive HSCT
- 11 of the 12 patients were MRD-negative prior to transplant



4 patients had remissions lasting at least 1 year, without additional maintenance therapy

CR, complete remission; CRh, complete remission with partial hematologic recovery; CRp, complete remission with incomplete platelet recovery; MRD, measurable residual disease.

Data cutoff: 31 March 2022

Maintenance after transplant: Patient 21 update

Diagnosed

- **40 yo F with *KMT2Ar* AML with *FLT3* TKD co-mutation**
- 3 prior lines of therapy including 7+3+midostaurin and HSCT

Revumenib started
- 163 mg q12h with strong CYP3A4i (Arm B)

CRp MRD-negative on AUGMENT-101

Proceeded to a 2nd HSCT; post transplant received 2 cycles azacytidine

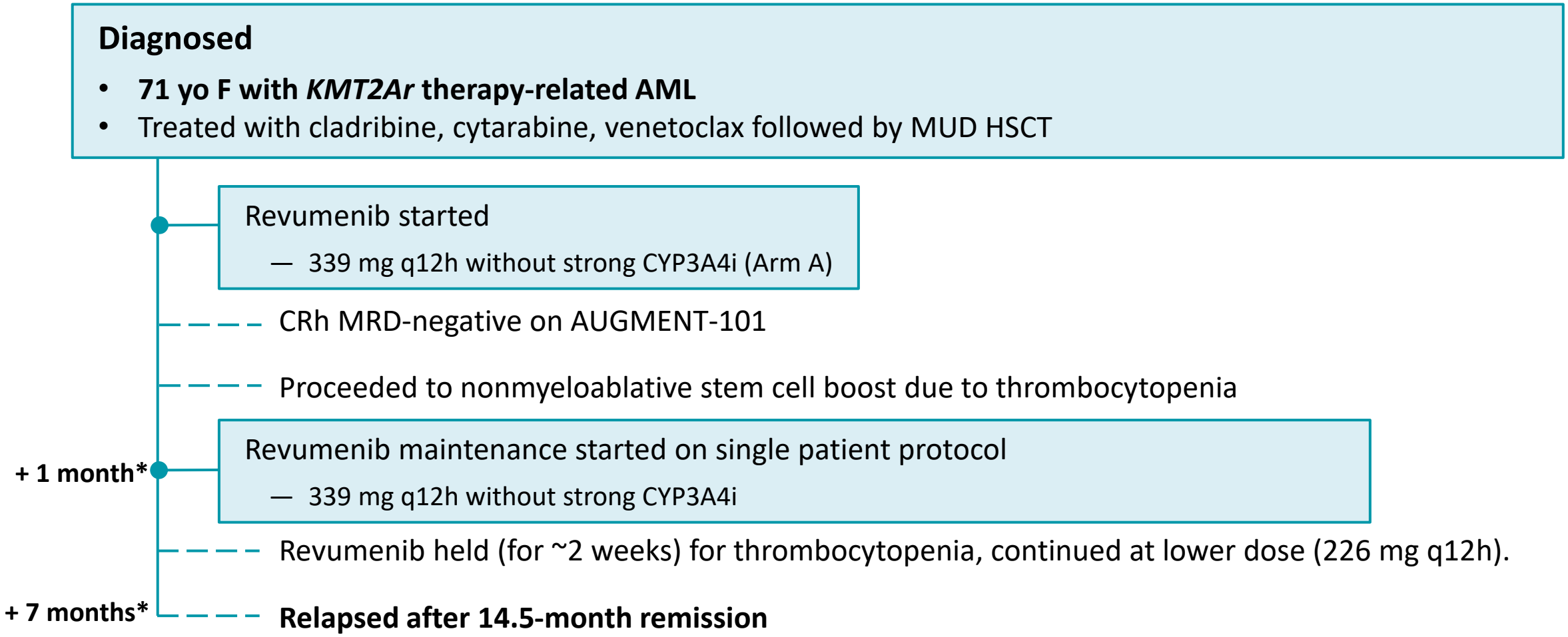
+ 6 months* Revumenib maintenance started on single patient protocol
- 163 mg q12h with strong CYP3A4i

Revumenib held twice (for ~1 month each) for thrombocytopenia, continued at lower dose (113 mg q12h). Platelets recovered to >100K by ~6 months post-transplant

+ 12 months* **MRD-negative by flow 1-year post-transplant**

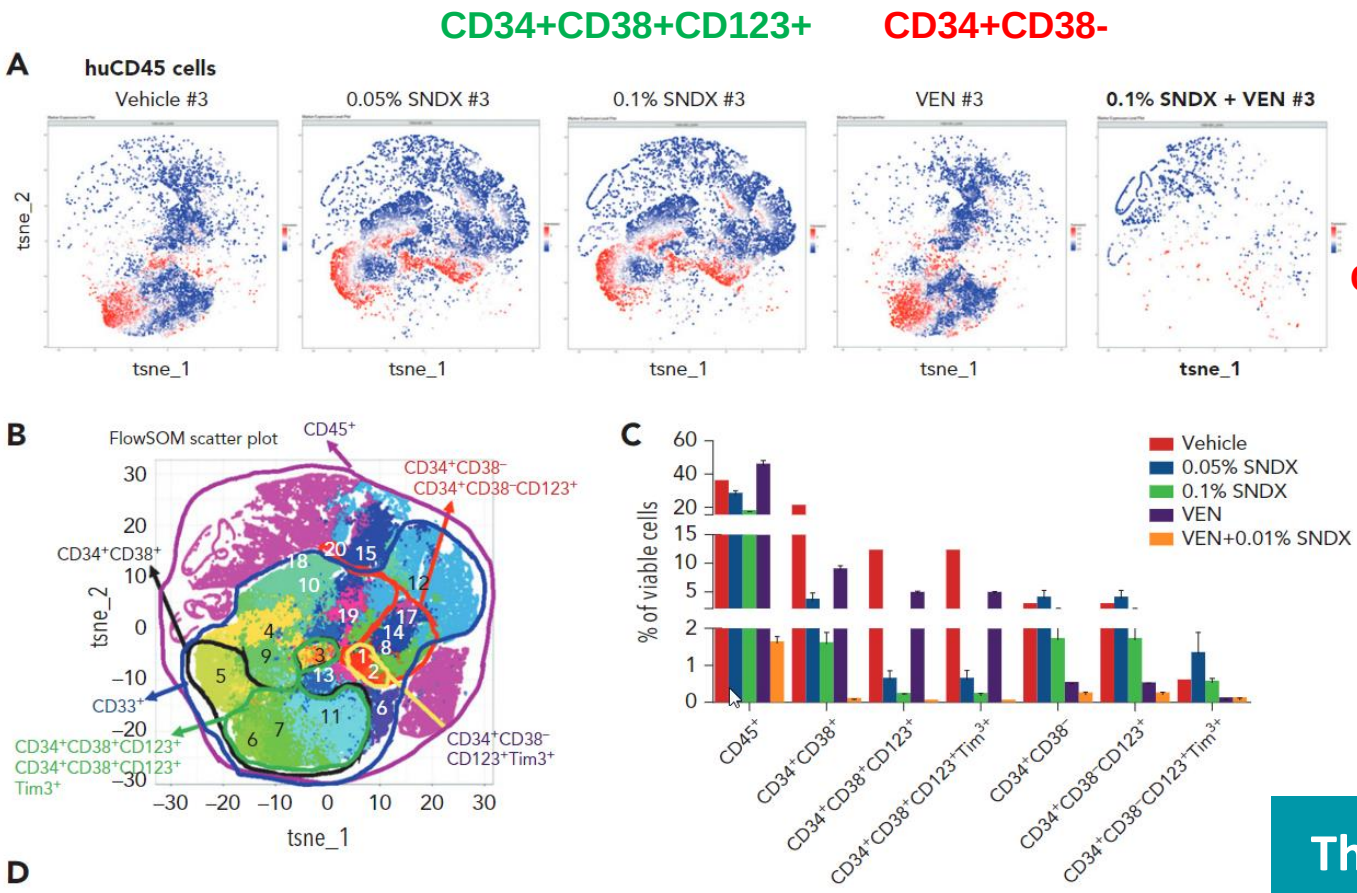
*Follow-up after transplant following response on AUGMENT-101.

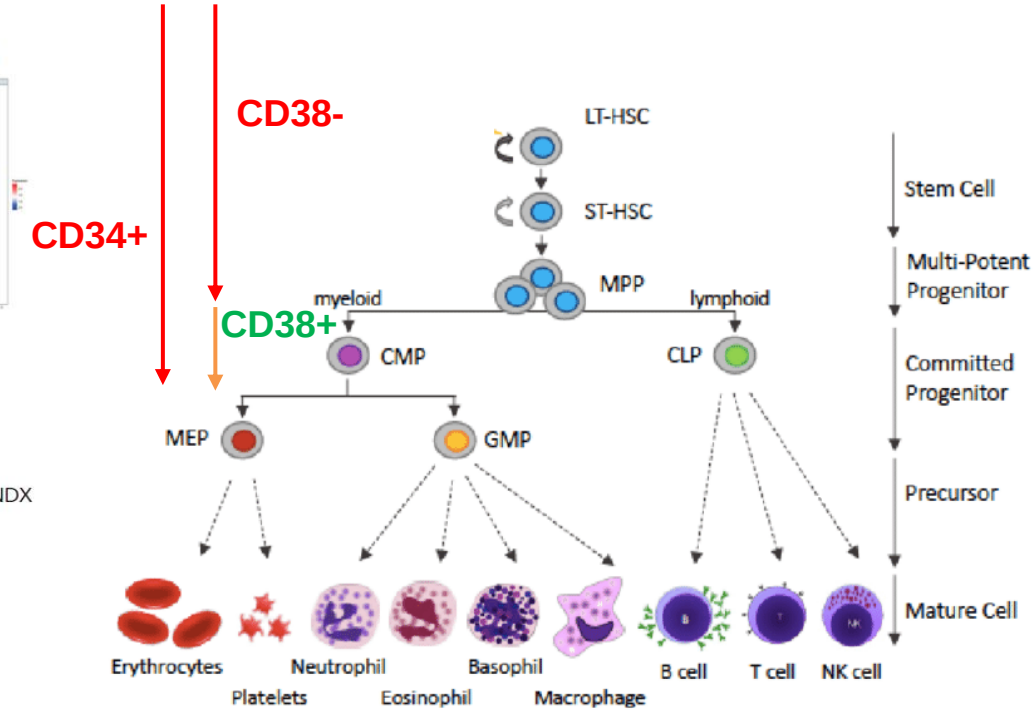
Maintenance after stem cell boost



*Follow-up after transplant following response on AUGMENT-101.
MUD, matched unrelated donor.

Preclinical data supporting rational combination of revumenib and the BCL2 inhibitor venetoclax





The combination effectively eliminated bulk and CD34+CD38+/CD34+CD38– stem/progenitor cells

Carter B. et al. Blood (2021) 138 (17): 1637–1641.

Revumenib downregulates transcription of *FLT3* and induces responses in patients with *FLT3* co-mutations

- Among *KMT2Ar/mNPM1:* 14 had *mFLT3*
  - 13/14 (93%) previously treated with a FLT3 inhibitor
- Overall response rate:
  - *KMT2Ar/mFLT3:* 2/3 (66%)
  - *mNPM1/mFLT3:* 3/11 (27%)
  - All responders previously treated with FLT3 inhibitor
- Revumenib leads to transcriptional downregulation of *FLT3*, a putative target of *MEIS1*[1,2]

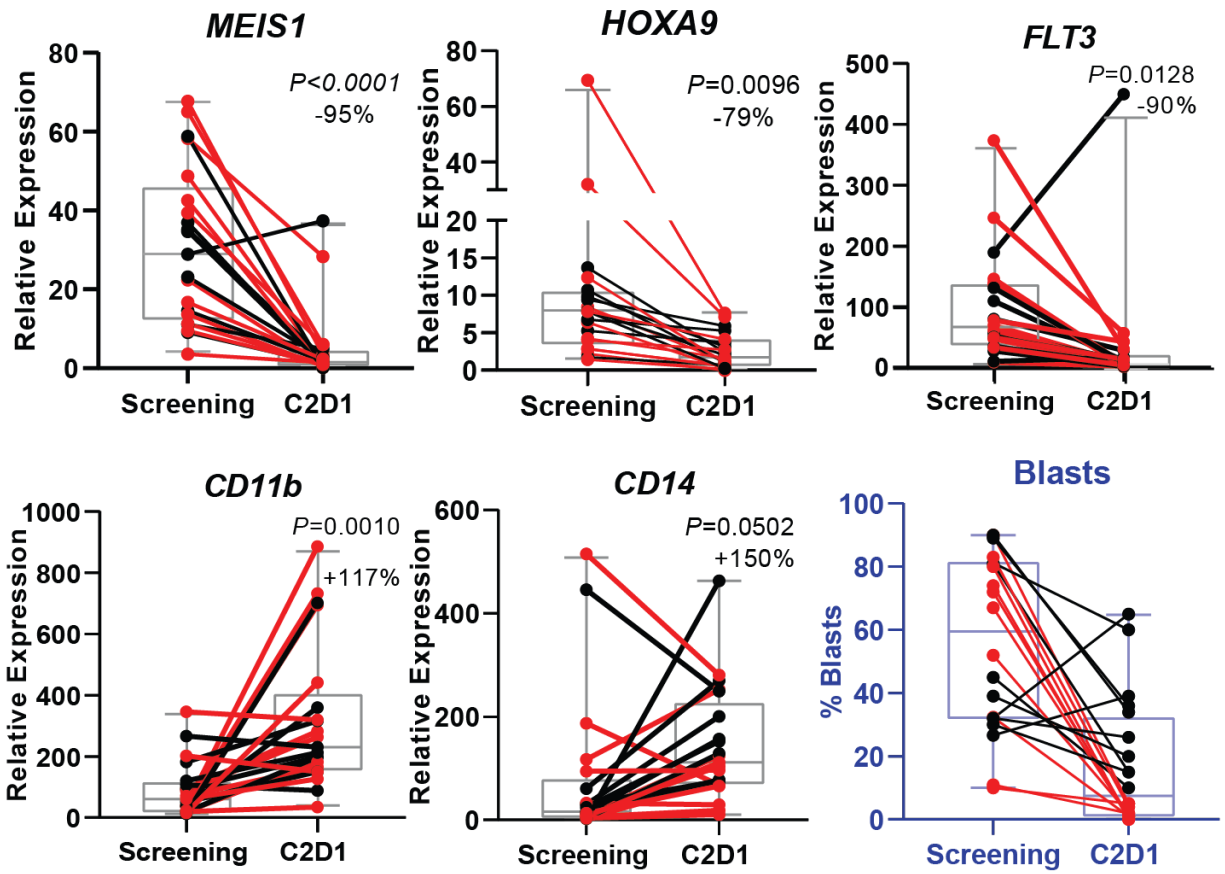
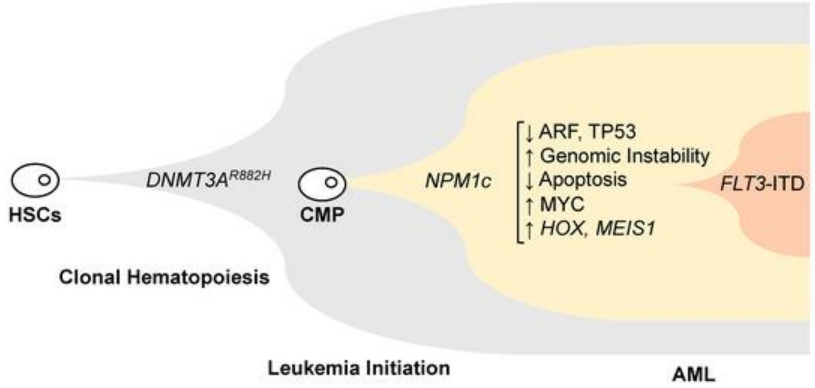
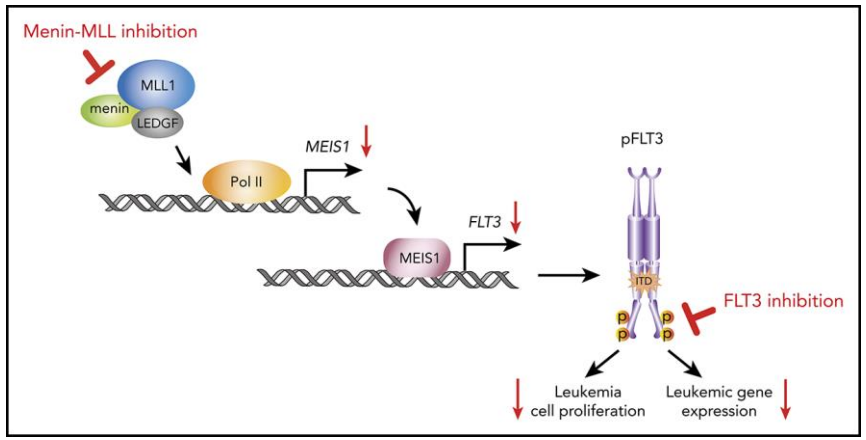


Figure includes a subset of patients (WT and mutated) that were evaluable by gene expression at screening and C2D1.

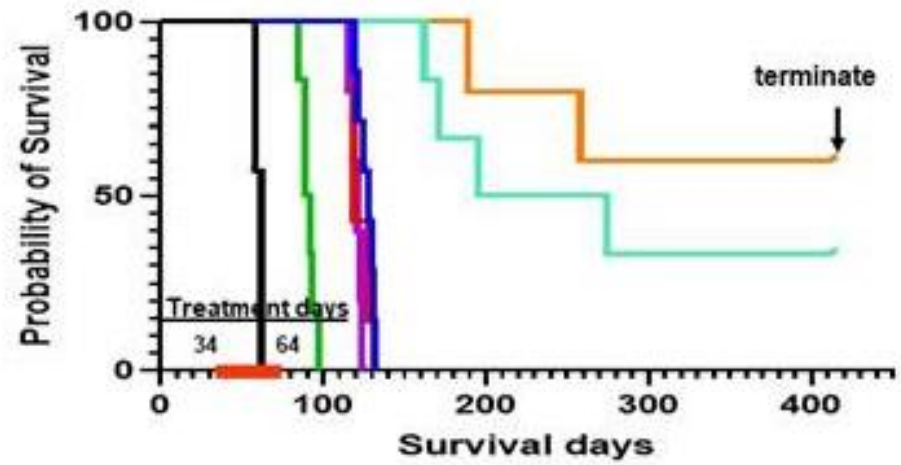
1. Kühn MW, et al. Cancer Discov. 2016 Oct;6(10):1166-1181;
2. Dzama MM, et al. Blood. 2020 Nov 19;136(21):2442-2456
C, cycle; D, day; WT, wild type.

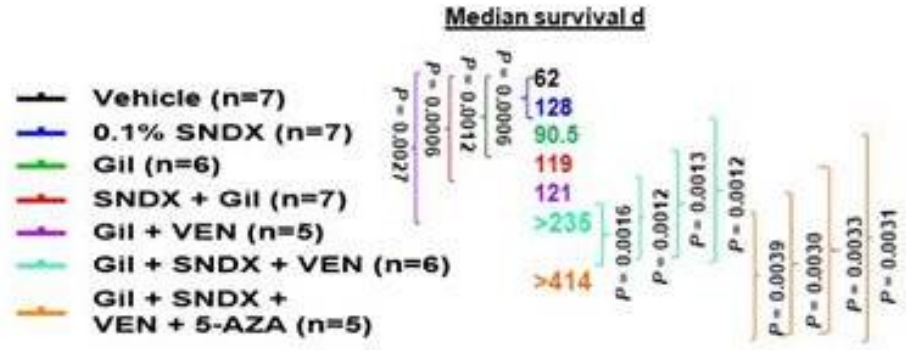
Preclinical data supporting transcriptional targeting of FLT3 with menin inhibition and combination with FLT3 inhibitors





PDX model: NPM1/FLT3-ITD/-TKD mutations





1. Zarka J, et al. Genes (Basel). 2020 Jun 12;11(6):649.
2. Kühn MW, et al. Cancer Discov. 2016 Oct;6(10):1166-1181;
3. Carter B, et al….. Andreff M (ASH 2022)

AUGMENT-101 Phase 2 pivotal trials underway in 3 distinct patient populations

AUGMENT-101

R/R
KMT2Ar (MLLr)
or *mNPM1*
acute leukemia

Dose:
Revumenib 163 mg q12h
with a strong CYP3A4 inhibitor

Independent, pivotal trials

64 adults + up to 20 peds	**AUGMENT-101-2A: *KMT2Ar* ALL**
64 adults + up to 20 peds	**AUGMENT-101-2B: *KMT2Ar* AML**
64 adults + up to 20 peds	**AUGMENT-101-2C: *mNPM1* AML**

Primary objective: CR/CRh*
Secondary objectives: Durability of CR/CRh, OS, transfusion independence

*Patients taken to HSCT can restart treatment with revumenib post-transplant.

Revumenib is the first investigational treatment to receive BTD for R/R KMT2Ar (MLLr) acute leukemia

Breakthrough Therapy Designation Granted for Revumenib for the Treatment of Adult and Pediatric Patients with Relapsed or Refractory KMT2A- rearranged Acute Leukemia

Robust dataset	Significant unmet need	Broad designation
Ph 1 data from all KMT2A R/R acute leukemia pts: • AML, ALL and MPAL • Adults and peds • With or without CYP3A4 inhibitor therapy	KMT2Ar leukemia occurs in up to 10% of all acute leukemias, including~80% of infant acute leukemias; median OS < 3 months	KMT2Ar leukemia recognized as one disease, regardless of pathologic designation or age of onset

Conclusions

Revumenib resulted in deep, durable responses in heavily pre-treated R/R *KMT2Ar* and *mNPM1* patients, and demonstrated a clinically manageable safety profile

- 30% of patients attained CR/CRh with a median duration of 9.1 months
- 78% of patients with CR/CRh attained MRD negativity

38% of responders proceeded to transplant

- Maintenance after transplant appears feasible, and is allowed in Pivotal portion of AUGMENT-101
- Median OS was 7 months in this R/R population

The safety profile is clinically manageable

- Only DLT was asymptomatic Grade 3 QTc prolongation observed in 10% in patients treated at doses meeting criteria for RP2D; 13% in patients treated at all doses tested
- Differentiation syndrome occurred in 16% of patients, all cases were Grade 2 and responded to management with steroids with or without hydroxyurea

Promising potential of future combination strategies

Dr. Eytan Stein

Chief, Leukemia Service Director, Program for Drug Development in Leukemia
Associate Attending Physician Memorial Sloan Kettering Cancer Center

Putting the Augment 101 data into perspective

Treatment goals for patients with relapsed/refractory acute leukemia

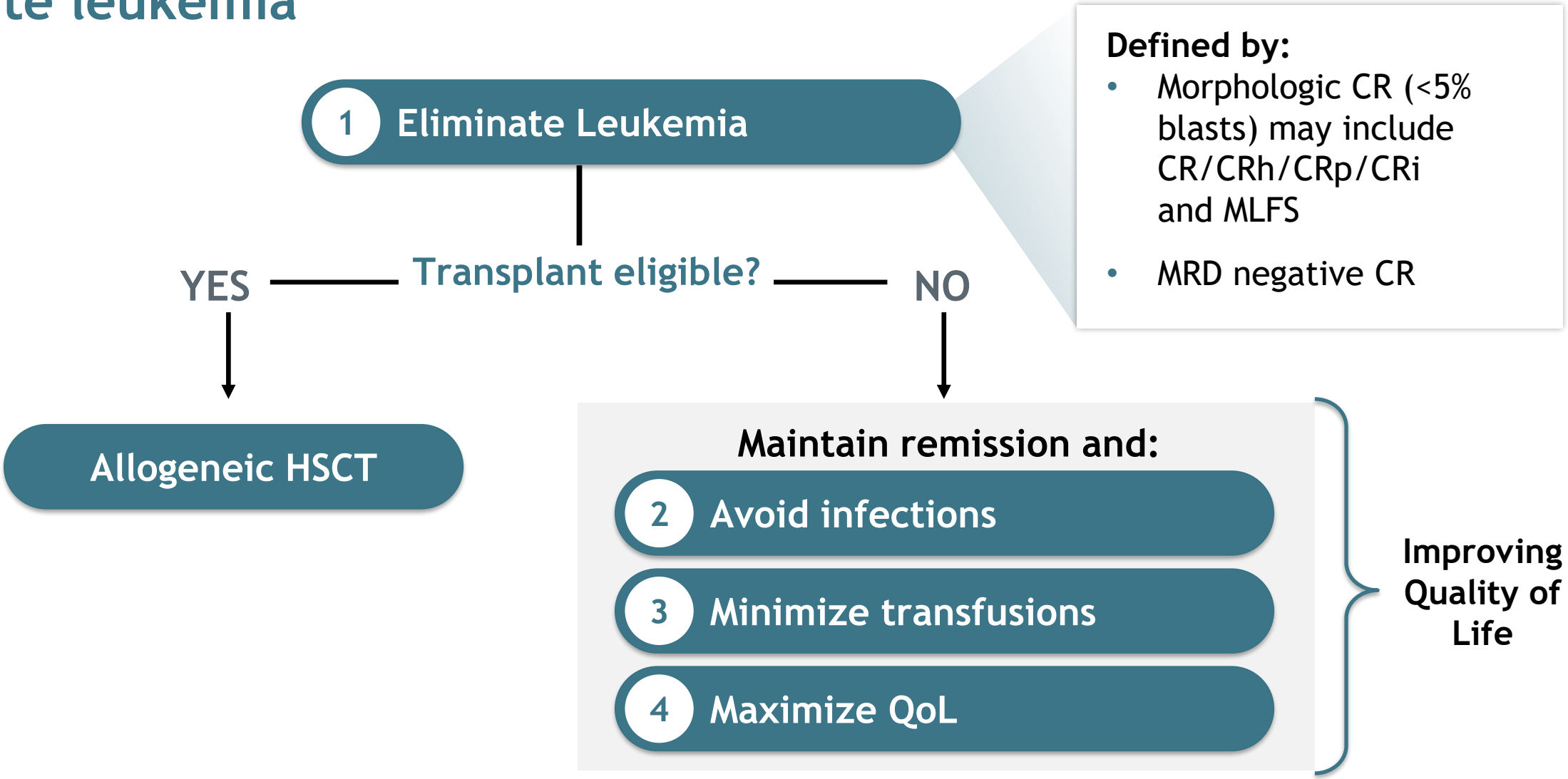
1 Eliminate Leukemia

Defined by:

- Morphologic CR (<5% blasts) may include CR/CRh/CRp/CRi and MLFS
- MRD negative CR

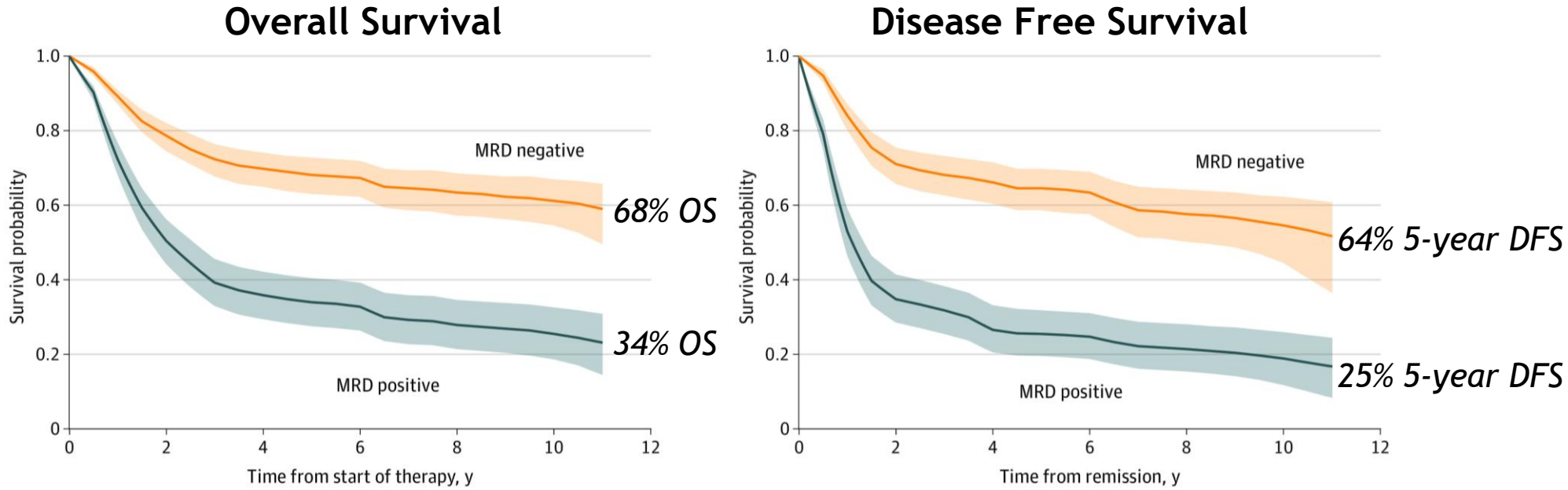
CR = normal blood counts; no transfusion; CRh = ANC >500, >50K Platelets; no transfusion; CRp = ANC >1000, Platelets <100K; no transfusion; CRi = ANC < 500; MLFS = clearance of blasts without blood count recovery that meets the criteria for CRh or CR

Treatment goals for patients with relapsed/refractory acute leukemia



CR = normal blood counts; no transfusion; CRh = ANC >500, >50K Platelets; no transfusion; CRp = ANC >1000, Platelets <100K; no transfusion; CRi = ANC < 500; MLFS = clearance of blasts without blood count recovery that meets the criteria for CRh or CR

MRD Negative response has been associated with increased success with transplant and survival in AML[1]

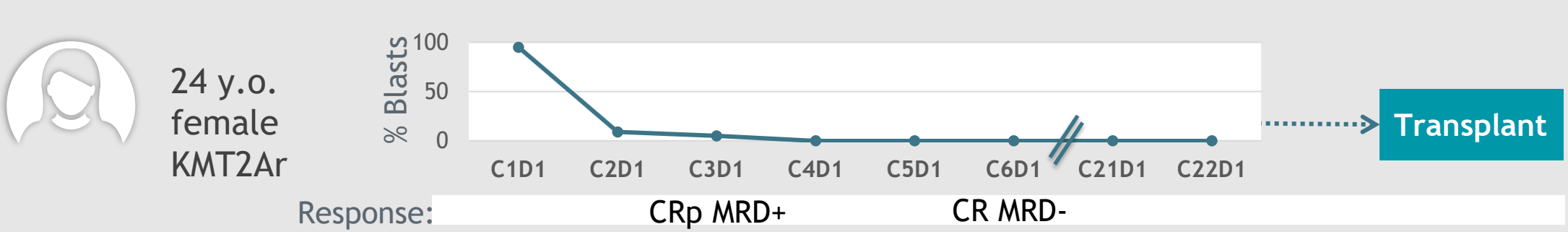


Systematic review based on a pooled analysis of >11,000 patients with AML

Association of MRD negativity with improvements in DFS and OS in patients with AML consistent across age, disease subtypes, and time of assessment

Source: 1.Short, NJ, et al., JAMA 2020 Dec 1;6(12):1890-1899.

Patient with AML, KMT2Ar t(6;11) achieves CR after five cycles



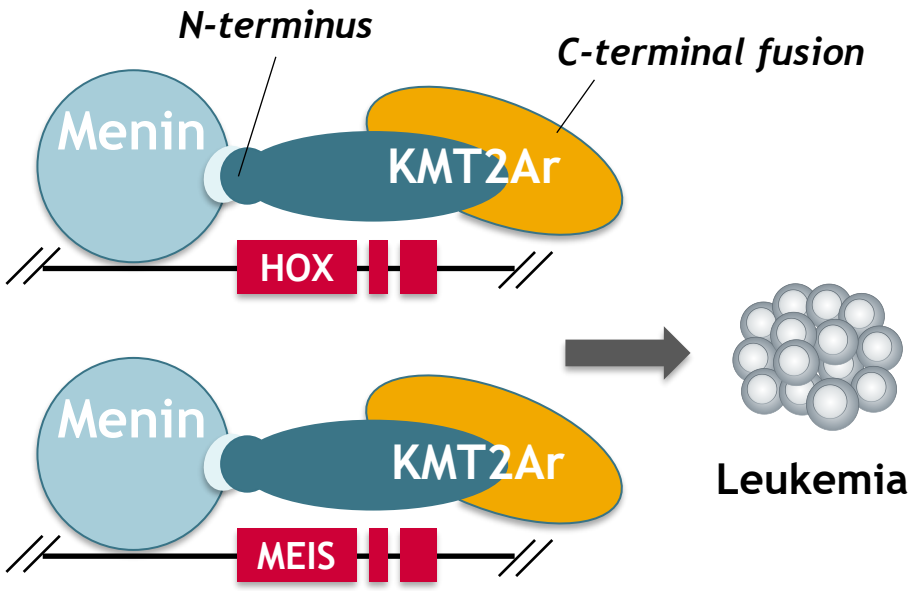
Demographics	24 y.o., female	
Diagnosis	AML with recurrent genetic abnormalities; KMT2Ar (t6;11)(q27;q23)	
Prior regimens and response	• Daunorubicin/cytarabine (Vyxeos™) • Fludarabine/cytarabine/idarubicin/G-CSF • Venetoclax/decitabine	Refractory to all
SNDX-5613 Dose	226mg q12h + voriconazole 1 cycle	
Dose reduction	None	
Response	CRp MRD+ at C3D1, converted to CR MRD- on C6D1, and went on to transplant after 22 months	

Patient went on to transplant after cycle 22

AML, Acute myeloid leukemia; CR, Complete Response; CRp, Complete Response incomplete platelet recovery; MRD, measurable residual disease; G-CSF, granulocyte colony stimulating factor; q12h, every 12 hours.

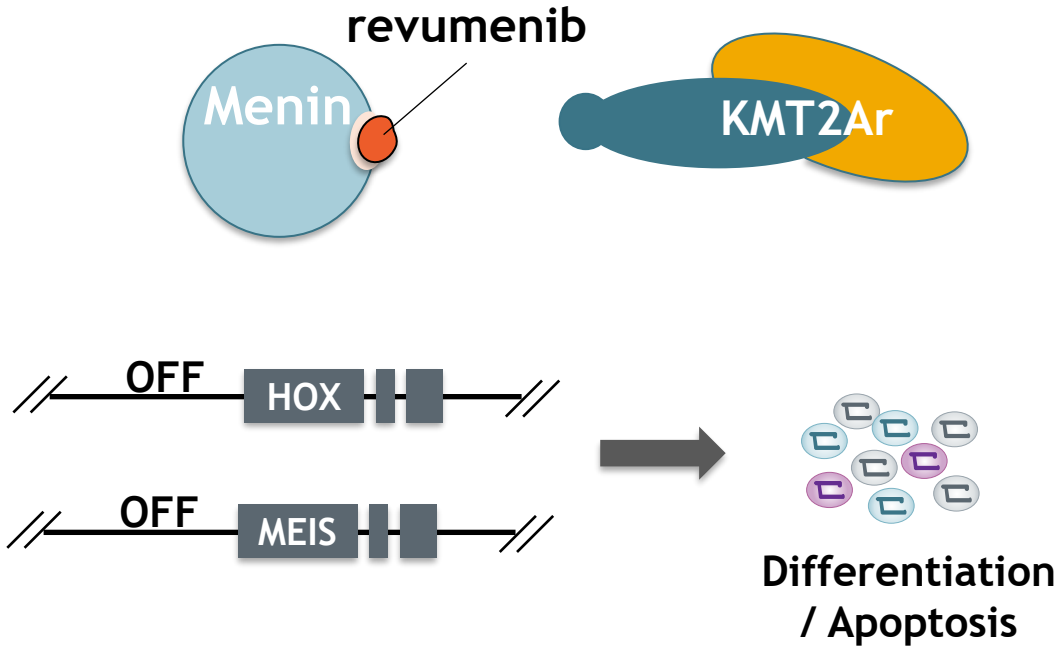
Revumenib turns off leukemic transcriptional programs by binding to Menin and displacing MLL complexes

MLLr Acute Leukemias



Gene transcription ON

Menin inhibition with revumenib



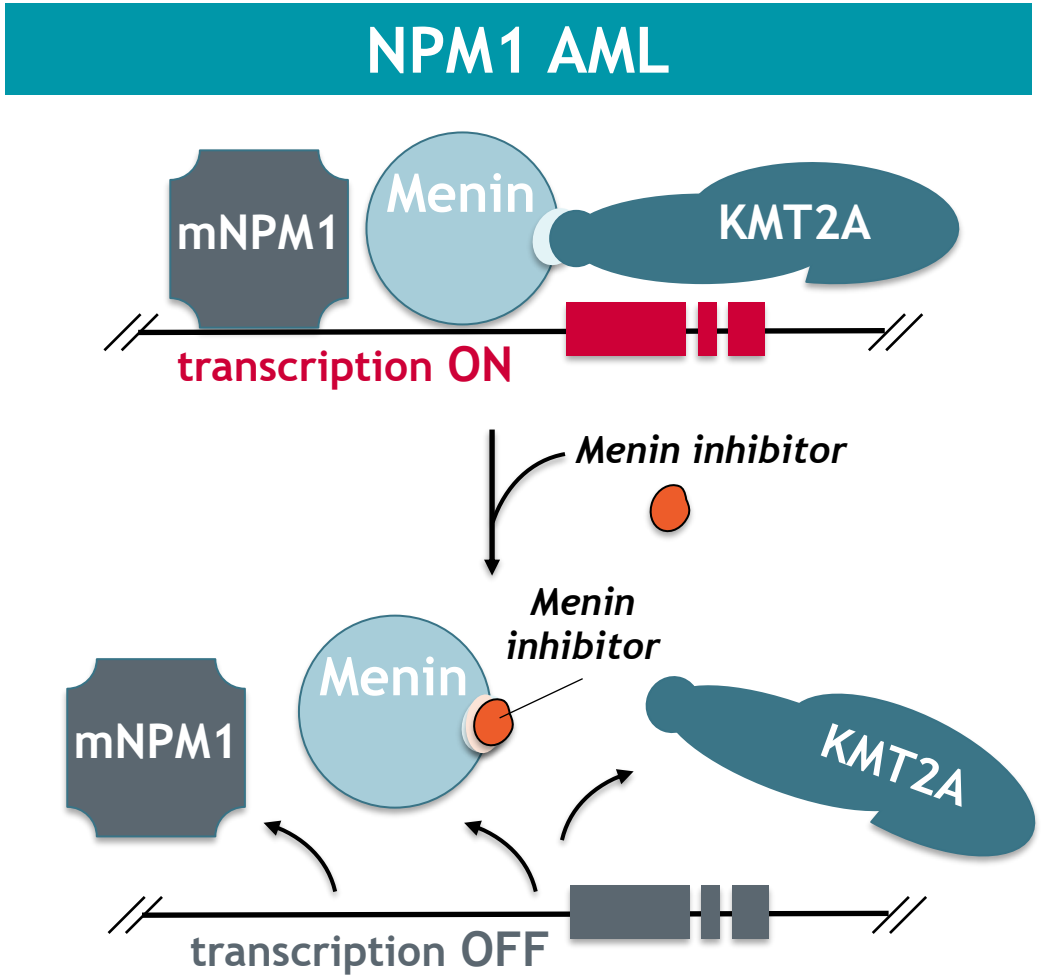
Gene transcription OFF

Adopted from: Uckelmann HJ, et al. Presented at ASH Annual Meeting, 2018

Mutant NPM1 acts in the nucleus to directly activate oncogenic gene expression in collaboration with KMT2A

- Mutant NPM1 protein shown to act as a direct transcription amplifier for several leukemic transcription factors including HOXA/B and MEIS1[1,2]

- Disruption of the Menin-MLL interaction through menin inhibition results in displacement of NPM1 from chromatin[1,2]



Source: Uckelmann HJ Cancer Discovery 2022; Wang XQD Cancer Discovery 2022; Figure adopted from: Uckelmann HJ, et al. Presented at EHA Annual Meeting, 2022

Menin inhibition provides a novel and efficacious option to treat both NPM1 mutant and KMT2A rearranged acute leukemia

Best Response, n (%)	Observed efficacy @ doses meeting RP2D criteria n=48	
Overall response rate (ORR)	25/48 (52%)	
Genetic alteration	KMT2Ar n=37	mNPM1 n=11
ORR	20/37 (54%)	5/11 (46%)
CR/CRh	10/37 (27%)	3/11 (27%)
CR/CRh MRD^{neg} rate	7/10 (70%)	3/3 (100%)

Dr. Briggs Morrison

President, Head of Research and Development at Syndax

Broadening the use of revumenib in acute leukemia

Significant unmet need remains in acute leukemia

No FDA-approved therapies targeting KMT2Ar (MLLr) or NPM1 acute leukemias

KMT2Ar: ~ 10% AML or ALL

- NCCN guidelines denote KMT2Ar predict poor prognosis
- Third-line treatment: Median overall survival of less than 3 months; 5% of patients achieve CR

mNPM1: ~ 30% AML

- Most frequent genetic alterations in AML
- Typically associated with favorable prognosis, however beneficial impact decreases with age
- 5-year overall survival rate for adult NPM1 AML is ~50%

Source: Issa, G. C., J. Zarka, K. Sasaki, W. Qiao, D. Pak, J. Ning, et al. (2021). Predictors of outcomes in adults with acute myeloid leukemia and KMT2A rearrangements. Blood Cancer J 11(9): 162. Dohner, H. et al. Blood, 2017; 129(4):424-447; Falini, B.et al. Blood 2011; 117(4):1109-1120. OS = overall response, CR = complete response;

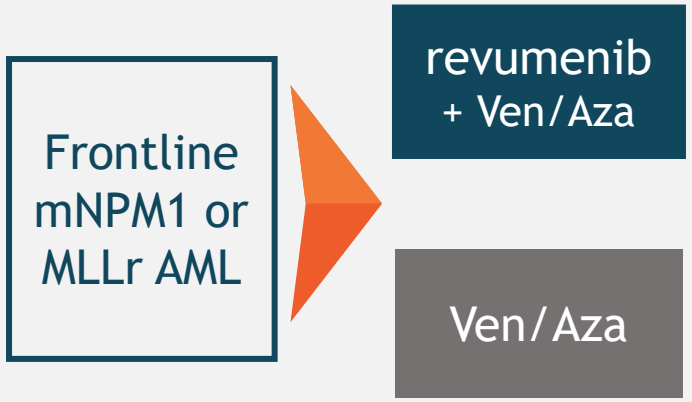
Trials underway to establish revumenib as a backbone of treatment for mNPM1 or MLLr acute leukemia

	Relapsed/Refractory	Front-Line	Maintenance
Revumenib Development	AUGMENT-101 AUGMENT-102	Beat AML acute myeloid leukemia	AUGMENT-101 INTERCEPT trial
Trial Description	Validates use of menin inhibition in NPM1 and MLLr acute leukemias, in monotherapy and chemotherapy combinations	Validates the use of menin inhibition with venetoclax/azacytidine, the commonly used regimen in older patients	**AUGMENT-101**: allows pts to restart Tx post-transplant **INTERCEPT**: examining conversion of MRD+ to MRD-

Multiple trials designed to expand opportunities in acute leukemia for revumenib

BEAT-AML: Frontline Ven/Aza combo

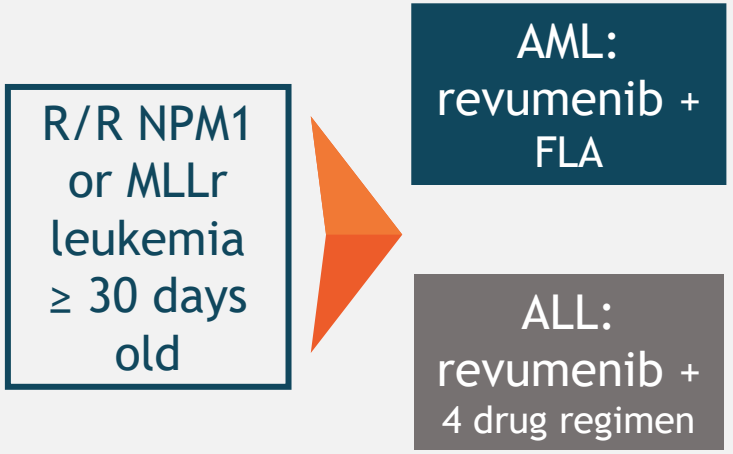
Phase 1/3; Frontline mNPM1 or MLLr AML
revumenib + Ven/Aza



Primary Endpoints:
- RP2D of combo
- CR/CRh rate, MRD- rate, OS

AUGMENT-102: R/R Chemo combo

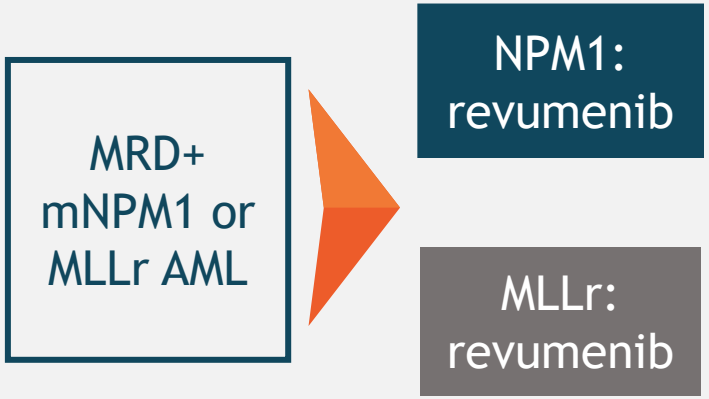
Phase 1; Relapsed or refractory mNPM1 or MLLr AML/ALL
revumenib + chemo



Primary Endpoints:
- Safety, tolerability, RP2D of combo

INTERCEPT: MRD-progression in AML

Phase 1; MRD positive mNPM1 or MLLr AML
revumenib monotherapy



Primary Endpoints:
- MRD- rate

Revumenib expansion opportunities in acute leukemia and solid tumors have potential to add meaningful value

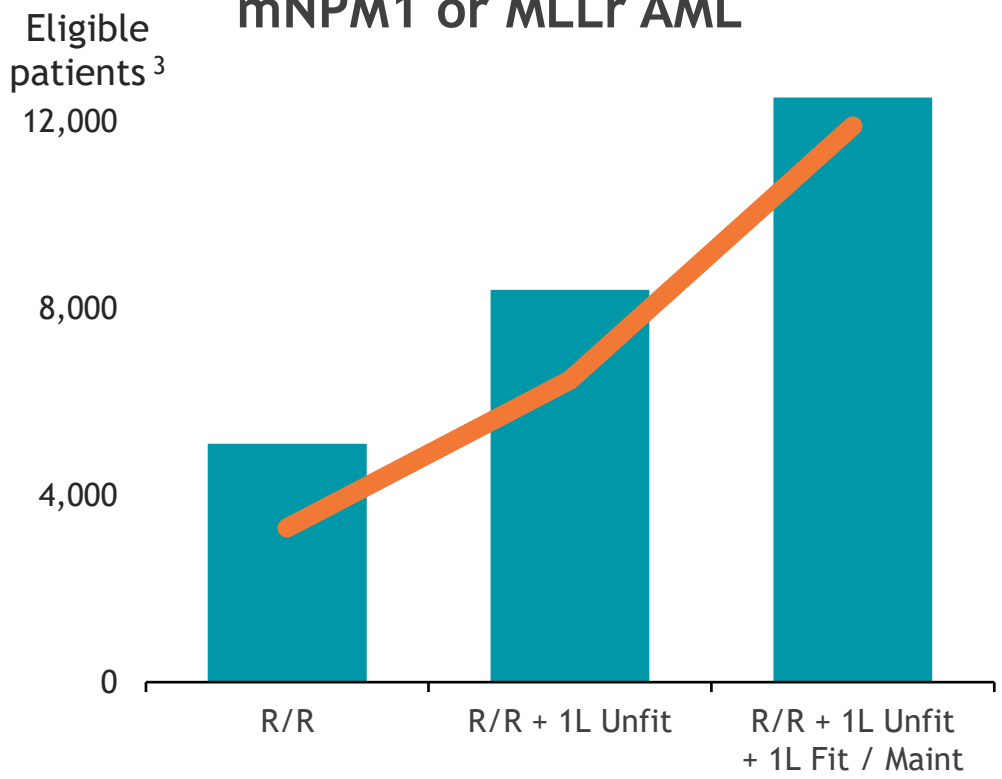
Potential first/best-in-class agent

- Clear activity in refractory, advanced mNPM1 and MLLr acute leukemia
- High percentage of MRD negative responses

Profile supports potential use in front-line and maintenance

- Well-tolerated safety profile, no discontinuations due to treatment related AE
- Preclinical data supports combos with venetoclax[1], chemotherapy[2]

Est. US market opportunity for mNPM1 or MLLr AML



Expansion into solid tumors represents another significant opportunity for value

[1] SMARTAnalyst 2020 [1] Carter, B., et al., Blood 2021; [2] Data on file; [3] SEER + Roche IR presentation Sept 2020 AML incidence estimates.

Thank you. Questions?

Syndax